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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/979,531	02/13/2002	Scott William Capeci	AA405	5959

27752 7590 04/06/2004

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EXAMINER

DOUYON, LORNA M

ART UNIT	PAPER NUMBER
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1751

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/979,531

**Applicant(s)**

CAPECI ET AL.

**Examiner**

Lorna M. Douyon

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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1. This action is responsive to the amendment filed on December 31, 2003.
2. The cancellation of claims 3, 11 and 12 is acknowledged. Claims 1-2, 4-10 and 13 are pending.
3. The rejection of claim 10 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment.
4. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Donoghue et al. (EP 0,816,485) is withdrawn in view of applicants' amendment.
5. The rejection of claims 1-13 under 35 U.S.C. 103(a) as being unpatentable over Bollier et al. (US Patent 4,828,721) is withdrawn in view of applicants' amendment.
6. The terminal disclaimer filed on December 31, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 6,555,514 has been reviewed and is accepted. The terminal disclaimer has been recorded.
7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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8. Claims 1-2, 4-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Raehse et al. (US Patent No. 5,382,377), hereinafter "Raehse".

Raehse teaches, in Examples 1 to 3, a process for the production of compacted granules which are later pressed to form tablets, the process comprising mixing together a tower powder (a total of 63.2 wt% spray dried powder) and carrier beads (equivalent to agglomerates or adjunct ingredients having a total of 28.5 wt%) in a 20 liter batch mixer equipped with a size reducing unit in the form of a cutter head, and mixing with the resulting mixture an aqueous sodium dodecyl benzenesulfonate (ABS) paste to form free-flowing premix, delivering the premix to a pellet press wherein the strands issuing from the cavity block are cut at a length of approx. 1.5 mm and drying the compacted granules in a discontinuous fluidized-bed dryer (see col. 13, line 25 to col. 15, line 5). In Example 3, a rounding machine was used before subsequent drying in the fluidized bed (see col. 14, lines 7-10). A twin-screw kneader (extruder) is the preferred homogenizing unit and the steps of homogenization, compaction and extrusion of the premix require only very short times, normally only a few minutes, preferably less than 5 minutes (see col. 5, lines 8-61). In general, more than 90% and preferably more than 95% of the granulated material has the particles size to be established in accordance with the invention (see col. 6, lines 55-57). Even though Raehse does not explicitly disclose the circularity, aspect ratio and the geometric standard deviation of the particle diameter, the spherical granules obtained in the process of Raehse would inherently possess the characteristics as those recited because same ingredients and process steps have been utilized. Hence, Raehse, anticipates the claims.

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9. Claims 1-2, 4-5, 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doumen et al. (US Patent No. 5,703,037), hereinafter "Doumen".

Doumen teaches a process for the manufacture of free flowing granules which comprises the steps of neutralizing anionic surfactant acid in an excess of alkali to form a paste, mixing the paste with one or more powders to form a granular product wherein at least one of the powders is spray dried and comprises anionic polymer and cationic surfactant, and optionally drying the granular product (see abstract). The paste and powders are mixed in a high shear mixer at a blade tip speed of from about 5 m/sec to about 50 m/sec and a total residence time of the mixing and granulation process is preferably in the order of from 0.1 to 10 minutes (see col. 6, lines 33-41). The ratio of the pasty mixture to powder should be chosen in order to maintain discrete particles at all stages of the process (see col. 6, lines 42-44). In Example 1, Doumen teaches a process for the manufacture of free flowing granules which comprises intimately mixing an aqueous surfactant paste and spray-dried powder having an apparent bulk density of 250 g/l in a twin screw extruder, extruding the resulting paste directly into a Loedige CB30 high speed mixer containing a mixture of 2 part zeolite A to 1 part finely divided light carbonate, the mixer operates on a continuous basis and discharges directly into a Loedige KM 300 continuous ploughshare mixer and the resulting agglomerates are transferred to a fluid bed drier, cooled in a fluid bed cooler and then classified through mesh sieves to remove oversize and fine particles (see col. 9, line 49 to col. 10, line 33). Doumen, however, fails to specifically disclose the geometric mean particle diameter of the granules with the recited geometric standard deviation, circularity and aspect ratio of the granules.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to reasonably expect the resulting granules in the process of Doumen to have a particle diameter and standard deviation within those recited because Doumen discloses that the granules have been classified through mesh sieves to remove oversize and fine particles, hence, leaving particles having particle diameters which would overlap those recited. In addition, the circularity and aspect ratio of the granules should also overlap those recited because same process steps and ingredients have been utilized.

10. Claims 6, 9, 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doumen as applied to the above claims, and further in view of Beimesch et al. (US Patent No. 6,391,844), hereinafter "Beimesch".

Doumen teaches the features as described above. Doumen, however, fails to teach recycling the fines from the fluid bed granulator to at least one mixer and the operating conditions of the fluid bed granulator.

Beimesch teaches further granulating agglomerates in a fluidizing apparatus wherein the conditions of the fluidizing apparatus include (i) from about 1 to about 10 minutes of mean residence time, (ii) from about 100 to about 300 mm of depth of unfluidized bed, (iii) not more than about 50 micron of droplet spray size, (iv) from about 175 to about 250 mm of spray height, (v) from about 0.2 to about 1.4 m/s of fluidizing velocity and (vi) from about 12 to about 100°C of bed temperature (see col. 3, line 64 to col. 4, line 6). Further agglomeration in the fluidized bed enhances granulation for producing free flowing high density granules (see col. 5, lines 41-

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46). Beimesch also teaches that an internal recycle stream of fine powder generated in the fluidizing apparatus can be fed into the mixer (see col. 4, lines 44-48).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to recycle fine powder from the fluidized bed to the mixer and to further agglomerate the granules of Doumen in the fluidizing apparatus of Beimesch because such process enhances granulation for producing free flowing high density granules as taught by Beimesch.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The references are considered cumulative to or less material than those discussed above.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

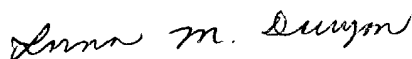
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lorna M. Douyon whose telephone number is (571) 272-1313. The examiner can normally be reached on Mondays-Fridays from 8:00AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on (571) 272-1316. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lorna M. Douyon  
Primary Examiner  
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